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REMARKS

Claims 62, 64, and 65 have been cancelled. Claims 1, 2, 4, 52, 53, and 66 have been allowed. Claims 3, 54, 55, 56, 57, 58, 59, 60, 61, and 63 have been amended. New claims 70 and 71 have been added. No new matter has been added by amendment. Reexamination and reconsideration of the claims as amended are respectfully requested.

Claim Rejections – 35 USC § 112, second paragraph

The Examiner rejects claims 3, and 55-64 under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner rejects claim 3, 55-56, 58-59, 61-62, and 64. The Applicant traverses the rejection but has cancelled claims 62 and 64 and has amended claims 55, 56, 58, 59, and 61 for clarification purposes and to expedite prosecution. Claim 3 has been amended and reads as follows, "The maize plant of claim 2, wherein genes controlling male sterility have been transferred into said maize plant through crossing that utilizes PH48V as a recurrent parent and wherein said plant has essentially the same morphology and physiology of inbred line PH48V other than the trait of male sterility." Claims 55 and 58 have been amended in a similar manner. Claim 61 has been amended and now reads, "The maize plant, or parts thereof, of claim 2, wherein genes controlling a qualitative trait have been transferred into said maize plant through crossing that utilizes PH48V as a recurrent parent and wherein said plant has essentially the same morphology and physiology of inbred line PH48V other than the trait of male sterility." The Examiner suggests that a new claim be directed towards a method of producing a maize plant comprising transforming the maize plant of claim 2 and another claim directed towards the plant produced by the method of transforming. Starting on page 1, line 34 and going through line 14 of page 3 of the specification it states that various genes, nuclear and cytoplasmic, have been used to control sterility in maize plants. In the specification on page 4, lines 7-19, it states, "Backcrossing can be used to transfer a specific desirable trait from one inbred or source to an inbred that lacks that trait. This can be accomplished, for example, by first crossing a superior Inbred (recurrent parent) to a donor inbred (non-recurrent parent), that carries the appropriate gene(s) for the trait in question. The progeny of this cross is then mated back to the

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superior recurrent parent followed by selection in the resultant progeny for the desired trait to be transferred from the non-recurrent parent." A hybrid developed from inbreds containing the transferred gene(s) is essentially the same as a hybrid developed from the same inbreds without the transferred gene(s)." The technique of backcrossing male sterility genes into an inbred maize plant is well known and well understood to one of ordinary skill in the art. The technique has been successfully used since the 1950's (see pages 585-586 of Wych, 1988, included in the information disclosure statement). The amendments contain no new matter. The Applicant requests reexamination and reconsideration of the claims as amended.

A new claim 70 has been added and is directed toward the method of transforming PH48V. The claim is not limited by a particular transgene as suggested by the Examiner. The Applicant believes that an amendment as suggested by the Examiner is limiting the scope to which the Applicant is entitled. Examples of transgenes are given in the specification. Applicant points out that the claim is to a method that is well known to one of ordinary skill in the art.

The Examiner rejects claim 64. Applicant has cancelled the claim.

Claim Rejections – 35 USC § 112, first paragraph

The Examiner rejects claims 54, 57, 60-61, 63-65, and 67-69 under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the application was filed, had possession of the claimed invention. Applicant traverses the rejection.

The Examiner rejects to claim 61. The claim has been amended and no longer includes the terms "value added" but now is limited to "qualitative traits". The Examiner rejects claim 64 because it is drawn to any "plant comprising one or more traits introgressed into the claimed variety by backcrossing or other traditional methods." Applicant traverses the rejection but has cancelled claim 64. The Examiner rejects to claims 54, 57, 60, 63, 65, and 67-69 because the claims are "broadly drawn to any hybrid produced by crossing the exemplified inbred line with any of a multitude of non-exemplified inbreds, or any descendent of the exemplified cultivars obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and undisclosed breeding partners." The claims now specify the F1 hybrid. The claims are now in condition for allowance. Claim 65 has been cancelled.

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Claims 67-69 are clearly directed to growing out an F(1) hybrid in which PH48V is a parent and searching for PH48V inbred seed. Due to the imperfect process of seed production parent seed can sometimes be contained in the hybrid seed bag. The claims merely claim the method of searching for inbred PH48V seed within a bag of hybrid seed. The method is also clearly described in the specification on page 5, line 21 through line 7 on page 6. The Applicant requests that the Examiner withdraw his rejection to claims 67-69.

As stated earlier the Examiner rejects claims wherein PH48V contains a trait that has been introduced through traditional means. Claims 3, 55, 58, and 61 have been amended to clearly indicate a PH48V plant that contains a trait that has been introduced using traditional methods. The Examiner has cited articles and states that they "teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant." The Examiner states that, "Hunsperger et al. teach that the Introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (column 3, lines 26-46)." This is not what is taught by Hunsperger et al. Hunsperger et al. teaches that a gene that results in dwarfism of a petunia plant can be incorporated into other genetic backgrounds of the petunia species (See column 2, line 67 to column 3, lines 1-4). Hunsperger et al. merely discusses that the level of the expression of that gene differed in petunia plants of different genetic backgrounds. Hunsperger et al. succeeded in incorporating the gene into petunia plants of different genetic backgrounds. Therefore Hunsperger et al. demonstrate that one of ordinary skill in the art can use traditional breeding methods to obtain maize plants containing genes that confer a qualitative trait. The specification provides ample disclosure of starting materials such as maize Inbred PH48V, a discussion of traditional breeding methods that may be used, and examples of transgenes and naturally occurring genes. Please note in Hallauer et al. (1988) on page 472, submitted in the information disclosure statement, it states that, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage."

The Examiner goes on to state that, "Kraft et al. teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotypic specific and loci-

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dependent in nature (page 323)." Applicant disagrees that the article states such points. Applicant assumes that the Examiner is trying to point out that one gene cannot be introduced into a plant using traditional breeding techniques such as backcrossing without also introducing closely linked genes into the plant. It is well understood in the relevant art that DNA surrounding the gene of the desired trait is introduced into the plant when traditional breeding techniques are utilized to insert a gene into a plant of interest. It is also understood in the art that introducing a gene into a plant variety such as PH48V is an insubstantial change to the variety. The World Seed Organization, on its web site, writes, "The concept of an essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-crossing and to fill the gap between Plant Breeder's Rights and patents." As determined by the UPOV Convention, essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering. The commercialization of an essentially derived variety needs the authorization of the owner on the rights vested in the initial variety." International Convention for the Protection of New Varieties of Plants, as amended on March 19, 1991, Chapter V, Article 14, Section 5(c), (emphasis added). A copy of the relevant portion of the UPOV Convention and the World Seed Organization web site is attached as Appendix B.

An example of how one of ordinary skill in the art can transfer a gene conferring a qualitative trait into a variety through backcrossing is demonstrated by the fact that the commercial market now distributes a multitude of products produced in this manner. Such conversion lines are easily developed without undue experimentation. Poehlman et al. (1995) on page 334, submitted in the information disclosure statement, states that, "A backcross-derived inbred line fits into the same hybrid combination as the recurrent parent inbred line and contributes the effect of the additional gene added through the backcross."

The Examiner goes on to state that, "Eshed et al. teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may effect quantitative traits in genetically complex and less than additive fashion (page 1815). The Applicant would like to first point out on page 1816, column 1, lines 1-5 of the Eshed et al. article it states, "Recent studies that detected epistasis of selected QTL in Drosophila (Long et al. 1995), soybean (Lark et al. 1995)

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and maize (Doebley et al.1995; Cockerham and Zeng 1996) did not show a less-than-additive trend." Emphasis added. Applicant also adds that transferring a qualitative trait does not require undue experimentation. Please note Hallauer et al. (1988) on page 472, submitted in the information disclosure statement, which states, "For single gene traits that are relatively easy to classify, the backcross method is effective and relatively easy to manage." In claims 3, 55, 58, and 61, the genes transferred into PH48V are now limited to qualitative traits either through the use of the term qualitative or through the type of trait identified. The claims are also limited to plants that are essentially unchanged from PH48V. Given the arguments and the amendments the Applicant requests reexamination and reconsideration of the claims.

As noted in the specification, the development of an inbred line is a time consuming and labor intensive activity. On average, between 10,000 to 20,000 lines are created and screened in order to develop any maize inbred line for which the Applicant files a patent application. Once developed, the inbred line is useful for two purposes: (1) to make commercial hybrids, and (2) as a source of breeding material for the development of new inbreds that retain the original inbred's desired characteristics. A breeder desiring to make a line with similar traits to PH48V would be greatly advantaged by being able to use PH48V as starting material. This is because the linked genes arranged through Applicant's breeding efforts, and fixed in PH48V, can be maintained in the progeny of PH48V by a breeder of ordinary skill in the art. For example, if a breeder of ordinary skill in the art desired a waxy-kernel corn version of PH48V, the breeder could cross PH48V to a waxy-kernel corn variety, select for progeny with the desirable traits of PH48V that also express the waxy kernel trait, and continue selecting for the traits of PH48V combined with waxy kernels. Optionally, the breeder could backcross to PH48V to obtain further genetic contribution from PH48V. The end result is the development of an inbred line with substantially all of the benefit of Applicant's work but with only a fraction of the effort.

Applicant has added new claim 71 which reads, "A method of producing a PH48V progeny inbred maize plant comprising obtaining a seed for which the plant of claim 2 is a parent and selfing said seed for successive filial generations to produce said PH48V progeny inbred maize plant." The claim is a method claim and one of ordinary skill in the art would know how to cross PH48V with another plant and self the successive generations. In *Ex parte Parks*, 30 USPQ 2d 1234 (B.P.A.I. 1994), the Board of Appeals stated, "Adequate description under the first paragraph of 35 U.S.C.

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112 does not require *literal* support for the claimed invention. Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed." In *J.E.M. Ag. Supply*, the Supreme Court also acknowledged the value of a utility patent in protecting the use of the line in breeding, when it stated that, "...a breeder can use a plant that is protected by PVP certificate to 'develop' a new inbred line while he cannot use a plant patented under §101 for such a purpose." *Id.* at 1873. In light of the amendments to the claims and the foregoing arguments the Applicant requests reconsideration of the rejection under the first paragraph of 35 U.S.C. 112.

CONCLUSION

Attached hereto is a marked-up version of the changes made to the specification and claims by current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

Claims 62, 64, and 65 have been cancelled. Claims 1, 2, 4, 52, 53, and 66 have been allowed. Applicant submits that amended claims 3, 54, 55, 56, 57, 58, 59, 60, 61, and 63, claims 67-69 and new claims 70 and 71 are in condition for allowance. No new matter has been added. Reexamination and reconsideration of the claims are respectfully requested. Reconsideration and early notice of allowability is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 62, 64, and 65 have been cancelled.

New claims 70 and 71 have been added.

Claims 3, 54, 55, 56, 57, 58, 59, 60, 61, and 63 as follows have been amended as follows.

3. (Amended) The maize plant of claim 2, wherein [said plant is male sterile] genes controlling male sterility have been transferred into said maize plant through crossing that utilizes PH48V as a recurrent parent and wherein said plant has essentially the same morphology and physiology of inbred line PH48V other than the trait of male sterility.

54. (Amended) A method for producing [a hybrid maize] an F1 hybrid seed comprising crossing the plant of claim 2 with a different maize plant and harvesting the resultant F1 hybrid maize seed.

55. (Amended) The maize plant, or parts thereof, of claim 2, wherein [the plant or parts thereof further comprise one or more transgenes for herbicide resistance] genes controlling herbicide resistance have been transferred into said maize plant through crossing that utilizes PH48V as a recurrent parent and wherein said plant has essentially the same morphology and physiology of inbred line PH48V other than the trait of herbicide resistance.

56. (Amended) The maize plant, or parts thereof, of claim 55, wherein at least one of the [transgenes] genes for herbicide resistance confers resistance to a chemical compound selected from the group consisting of imidazolinone,

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sulfonylurea, Glyphosate, glufosinate, L-phosphinothricin, triazine and benzonitrile.

57. (Amended) A method for producing [a hybrid maize] an F1 hybrid seed comprising crossing the plant of claim 55 with a different maize plant and harvesting the resultant F1 hybrid maize seed.

58. (Amended) The maize plant, or parts thereof, of claim 2, wherein [the plant or parts thereof further comprise one or more transgenes for pest or disease resistance] genes controlling pest or disease resistance have been transferred into said maize plant through crossing that utilizes PH48V as a recurrent parent and wherein said plant has essentially the same morphology and physiology of inbred line PH48V other than the trait of pest or disease resistance.

59. (Amended) The maize plant, or parts thereof, of claim 58, wherein at least one of the [transgenes] genes for pest or disease resistance encodes a Bacillus Thuringiensis endotoxin.

60. (Amended) A method for producing [a hybrid maize] an F1 hybrid maize seed comprising crossing the plant of claim 58 with a different maize plant and harvesting the resultant F1 hybrid maize seed.

61. (Amended) The maize plant, or parts thereof, of claim 2, wherein [the plant or parts thereof further comprise one or more transgenes that confer or contribute to a value added trait] genes controlling a qualitative trait have been transferred into said maize plant through crossing that utilizes PH48V as a recurrent parent and wherein said plant has essentially the same morphology and physiology of inbred line PH48V other than the trait of male sterility.

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63. (Amended) A method for producing [a hybrid maize] an F1 hybrid maize seed comprising crossing the plant of claim 61 with a different maize plant and harvesting the resultant F1 hybrid maize seed.

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What is an "Essentially Derived Variety"?

The concept of essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-crossing and to fill the gap between Plant Breeder's Rights and patents, gap which was becoming important due to the development of the use of patented genetic traits in genetic engineering.

An essentially derived variety is a variety which is distinct and predominantly derived from a protected initial variety, while retaining the essential characteristics of that initial variety.

As indicated as an example in the UPOV Convention, essentially derived varieties may be obtained by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, back-crossing, or transformation by genetic engineering.

The commercialization of an essentially derived variety needs the authorization of the owner of the rights vested in the initial variety.

The concept of essentially derived variety does not at all abolish the Breeder's Exemption, as free access to protected plant varieties for breeding purposes is maintained. It is not a threat to biodiversity. On the contrary, it favors biodiversity, encouraging breeders developing and marketing original varieties.

Appendix B
Serial No. 09/490,666

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INTERNATIONAL CONVENTION
FOR THE
PROTECTION OF NEW VARIETIES OF PLANTS

of December 2, 1961, as revised
at Geneva on November 10, 1972,
on October 23, 1978, and
on March 19, 1991

adopted by the Diplomatic Conference

on March 19, 1991

reproduced from UPOV Publication No. 438(E)

issue No. 63 of "Plant Variety Protection"

1991 Act of the Convention

Article 12Examination of the Application

Any decision to grant a breeder's right shall require an examination for compliance with the conditions under Articles 5 to 9. In the course of the examination, the authority may grow the variety or carry out other necessary tests, cause the growing of the variety or the carrying out of other necessary tests, or take into account the results of growing tests or other trials which have already been carried out. For the purposes of examination, the authority may require the breeder to furnish all the necessary information, documents or material.

Article 13Provisional Protection

Each Contracting Party shall provide measures designed to safeguard the interests of the breeder during the period between the filing or the publication of the application for the grant of a breeder's right and the grant of that right. Such measures shall have the effect that the holder of a breeder's right shall at least be entitled to equitable remuneration from any person who, during the said period, has carried out acts which, once the right is granted, require the breeder's authorization as provided in Article 14. A Contracting Party may provide that the said measures shall only take effect in relation to persons whom the breeder has notified of the filing of the application.

CHAPTER VTHE RIGHTS OF THE BREEDERArticle 14Scope of the Breeder's Right

(1) [Acts in respect of the propagating material] (a) Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:

- (i) production or reproduction (multiplication),
- (ii) conditioning for the purpose of propagation,
- (iii) offering for sale,
- (iv) selling or other marketing,
- (v) exporting,
- (vi) importing,
- (vii) stocking for any of the purposes mentioned in (i) to (vi), above.

(b) The breeder may make his authorization subject to conditions and limitations.

(2) [Acts in respect of the harvested material] Subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating material of the protected variety shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material.

(3) [Acts in respect of certain products] Each Contracting Party may provide that, subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of products made directly from harvested material of the protected variety falling within the provisions of paragraph (2) through the unauthorized use of the said harvested material shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said harvested material.

(4) [Possible additional acts] Each Contracting Party may provide that, subject to Articles 15 and 16, acts other than those referred to in items (i) to (vii) of paragraph (1)(a) shall also require the authorization of the breeder.

(5) [Essentially derived and certain other varieties] (a) The provisions of paragraphs (1) to (4) shall also apply in relation to

(i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,

(ii) varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety and

(iii) varieties whose production requires the repeated use of the protected variety.

(b) For the purposes of subparagraph (a)(i), a variety shall be deemed to be essentially derived from another variety ("the initial variety") when

(i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,

(ii) it is clearly distinguishable from the initial variety and

(iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

(c) Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

Article 15

Exceptions to the Breeder's Right

(1) [Compulsory exceptions] The breeder's right shall not extend to

(i) acts done privately and for non-commercial purposes,

(ii) acts done for experimental purposes and

(iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties.

(2) [Optional exception] Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting,

ATCC

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The American Type Culture Collection (ATCC) has received your deposit of seeds in connection with the filing of an application for patent. The following information is provided to fulfill Patent Office requirements.

Name and Address of Depositor:

Pioneer Hi-Bred International, Inc.
Attn: Kim M. Hagemann
7100 NW 62nd Avenue
PO BOX 1000
Johnston, IA 50131-1000

DOCKETED

JUN 10 2002

Deposited on Behalf of:

Pioneer Hi-Bred International, Inc.

Date of Receipt of Seeds by the ATCC:

May 3, 2002

Scientific Description

Depositor's Reference Case No. **Patent Designation**

Inbred corn (maize) seed, Source C1KEK11093 PF PH48V

1203

PTA-4263

The ATCC understands that:

1. The deposit of these seeds does not grant ATCC a license, either express or implied, to infringe the patent, and our release of these seeds to others does not grant them a license to infringe the patent.
2. If these seeds should die or be destroyed during the effective term of the patent, it shall be your responsibility to replace them with living seeds of the same type. It is also your responsibility to supply a sufficient quantity for distribution for the deposit term.

Prior to the issuance of a U.S. Patent, the ATCC agrees in consideration for a one-time service charge, not to distribute these seeds or any information relating thereto or to their deposit except as instructed by the depositor or relevant patent office. After a relevant patent issues, and we are instructed to release the seeds, they will be made available for distribution to the public without any restrictions.

The ATCC agrees to maintain the seeds for a period of 30 years from deposit date, or 5 years after the most recent request for a sample, whichever is longer.

We will inform you of requests for the seeds for 30 years from date of deposit.

The seeds were tested May 8, 2002 and were viable.

American Type Culture Collection

By Marie Harris
Marie Harris, Patent Specialist
ATCC Patent Depository

Date: May 28, 2002